

REMARKS

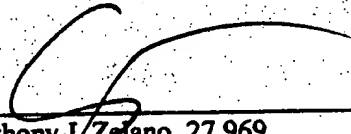
Whereas the inventive process of this application achieves higher total yields (page 9, lines 1-3) in comparison to the table on page 12, it has been discovered that the purity values recited in claim 4 were those for the prior art since they are derived from the mentioned table.

New claims 13 and 14 correspond to the isolated and isolated and purified forms of the compound recited in claim 2 of parent USP 6,121,465. See page 3, both full paragraphs.

As is clear of record, 6 β , 7 β ; 15 β , 16 β -dimethylene-3-oxo-17 α -pregn-4-ene-21,17-carbolactone is known and has been prepared in the past. See, e.g., the references of record, e.g., example 2 of USP 4,904,462, example H of USP 4,435,327, etc.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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Attorney Docket No.: SCH-1664 C1

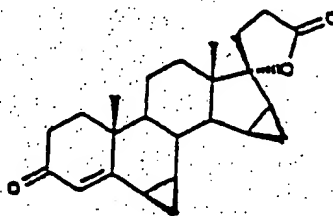
Date: September 18, 2002

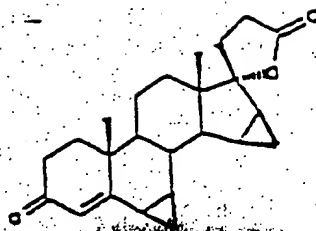
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Name: James A. Miller
Signature: James A. Miller
Date: September 18, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

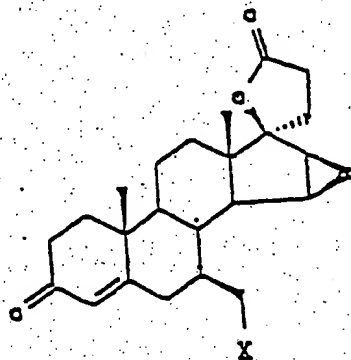
Please amend the claims as follows:

5. (Twice Amended) A composition comprising 6 β ,7 β ; 15 β ,16 β -dimethylene-3-oxo-17 α -pregn-4-ene-21,17-carbolactone [of claim 4], a pharmaceutically acceptable carrier, and less [then] than 0.2% by weight of said compound of the contaminants



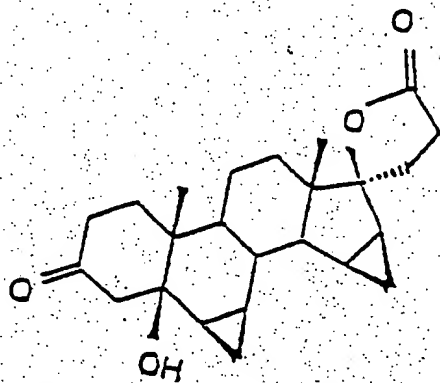


and



wherein X is an anion of an acid which is effective to open said 6 β , 7 β -methylene group.

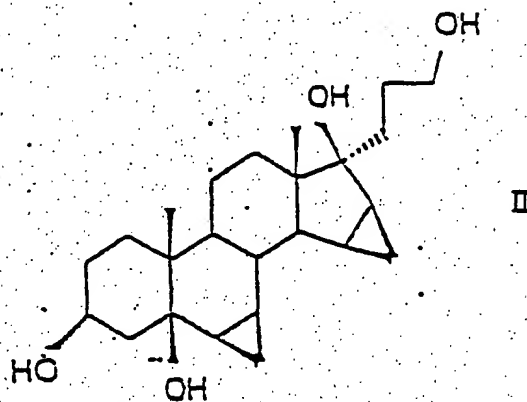
10. (Amended) A composition comprising
 - (a) 6 β , 7 β ; 15 β , 16 β -dimethylene-3-oxo-17 α -pregn-4-ene-21,17-carbolactone [of claim 4] made by a process comprising dehydrating a compound of Formula III,



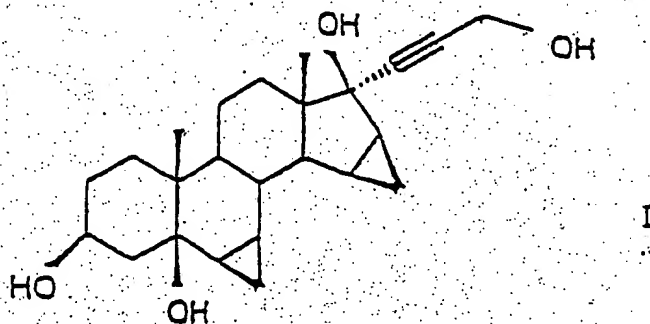
III

which was made by oxidizing in the presence of a ruthenium salt a compound of Formula

II,

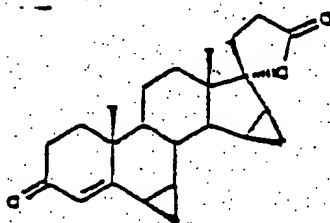


which was made by catalytically hydrogenating a compound of Formula I

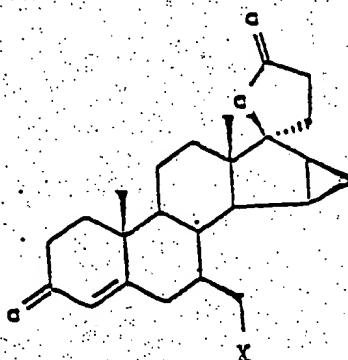


(b) a pharmaceutically acceptable carrier; and

(c) less [then] than 0.2% by weight of said compound (a) of the byproducts of said preparation process which are



and



wherein X is an anion of an acid which is effective to open said 6 β , 7 β -methylene group.

12. (Amended) A compound of claim [6] 10, wherein in said process, said dehydrating is performed after said compound of Formula III is isolated from the medium in which it is prepared.